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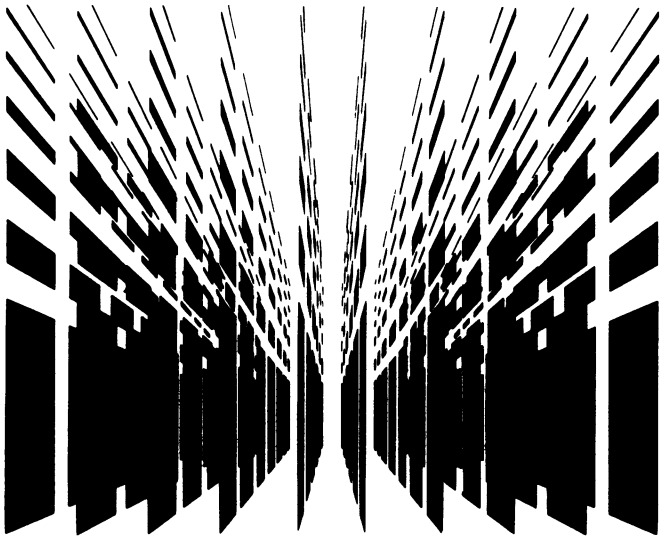

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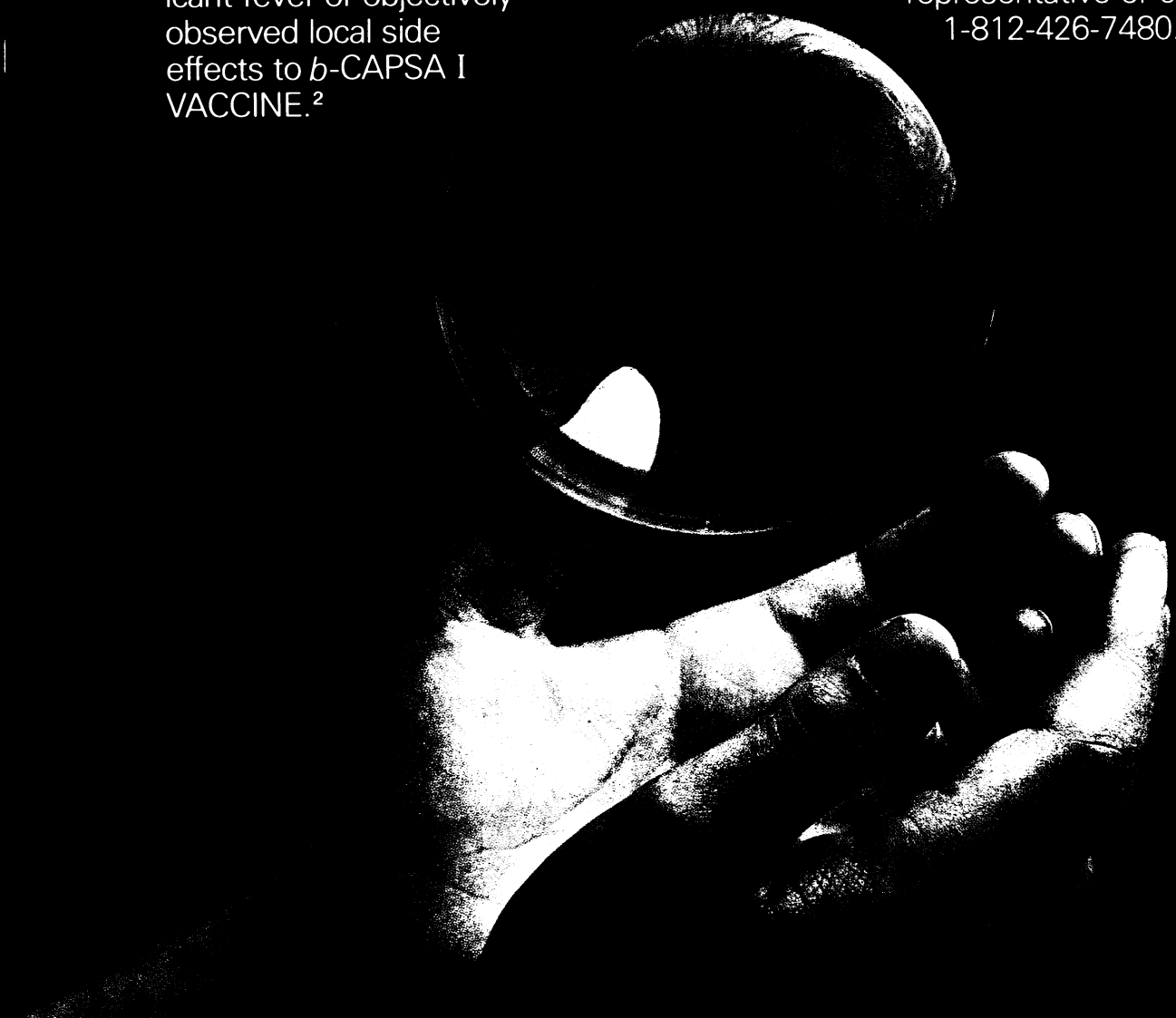

b-CAPSA™ I VACCINE

(Haemophilus b Polysaccharide Vaccine)

BRIEF SUMMARY

DESCRIPTION

b-CAPSA I VACCINE (Haemophilus b Polysaccharide Vaccine) is a sterile, lyophilized vaccine for subcutaneous administration. It is the capsular polysaccharide purified from the bacterium, *Haemophilus influenzae* type b, strain Eag and is a polymer of ribose, ribotol, and phosphate.[1]

Lactose is included in the vaccine at a concentration of 2.5 mg per 0.5 ml dose to improve product stability.[2] The lyophilized vaccine contains 25 μg of purified Haemophilus b polysaccharide per dose. The reconstituted vaccine contains thimerosal (mercurial derivative) 1:10,000 and sodium chloride for isotonicity. When reconstituted, *b*-CAPSA I VACCINE is a clear, colorless liquid.

CLINICAL PHARMACOLOGY

Haemophilus influenzae type b is the most common cause of bacterial meningitis and a leading cause of serious, systemic bacterial diseases in young children in the United States. This vaccine will not stimulate protection against other types of *Haemophilus influenzae* or other microorganisms that cause meningitis or septic disease.

Several population-based studies conducted within the last 10 years in the U.S. indicate that a child's cumulative risk of developing systemic *Haemophilus influenzae* b (Hib) disease at some time during the first 5 years of life is about 1 in 200.[3] About 60% of the children have meningitis and 40% other systemic diseases, such as cellulitis, epiglottitis, pericarditis, pneumonia, sepsis, or septic arthritis.[3] In these U.S. studies, about 35-40% of systemic Hib disease has occurred in children 18 months of age or older. In contrast, a recent prospective, five-year analysis of all children in Finland indicated that 60% of bacteremic Hib disease occurred in children 18 months of age or older and 45% in those 2 or more years of age.[4]

The incidence of systemic Hib disease is increased in certain children, e.g., Eskimo[5] and American Indian[6] children, patients with asplenia, sickle cell disease,[7] and antibody deficiency syndromes.[8] Recent studies also indicate that *Haemophilus influenzae* b can cause outbreaks of systemic disease among previously healthy children attending nursery school or day care, and that attendance at day care significantly increases the risk of developing systemic Hib disease.[9-11] Furthermore, the risk of acquiring systemic Hib disease for a child in intimate contact with one who has developed such a disease is up to 400 times that of a child in the general population.[9]

Hib diseases usually can be treated successfully. Even with appropriate antibiotic therapy, however, the mortality rate of Hib meningitis[12] and other bacteremic diseases can be 5%, and serious, long-term neurologic sequelae have been observed in 19-45% of survivors of meningitis.[3, 13] Up to 20% of *Haemophilus influenzae* b isolated in the USA from patients with systemic disease are resistant to ampicillin,[12, 14] and the mortality rate of meningitis is significantly greater when it is caused by ampicillin-resistant than by ampicillin-sensitive *Haemophilus influenzae* b.[12] Moreover, resistance to chloramphenicol and to multiple antibiotics has emerged.[14] When properly administered, rifampin can prevent bacteremic Hib disease among contacts at risk,[15] and its use for this purpose has been recommended by health authorities.[15, 16] Implementation of those recommendations can be difficult, however, especially in the setting of a large group. Thus, the strategy of controlling Hib disease by antibiotics has deficiencies.

The capsular polysaccharide of *Haemophilus influenzae* b (Haemophilus b polysaccharide) is its principal virulence factor. Anti-Haemophilus b polysaccharide antibody mediates complement-dependent bacteriolysis and opsonization *in vitro* and protects experimentally infected animals. Hyperimmune animal serum was used successfully to treat invasive human Hib diseases in the pre-antibiotic era, and antibody to the capsular polysaccharide was reported to be the protective component of that serum.[17]

For these reasons, Haemophilus b polysaccharide has been purified for use as a vaccine to prevent Hib diseases. More than 60,000 children and several hundred adults have been vaccinated with Haemophilus b polysaccharide in studies conducted in multiple centers.[4, 18-23] Adverse reactions have been mild and transient. Adults and older children uniformly produce a long-lived, non-boostable antibody response.[4, 18-20] Children respond variably according to their age: infants respond less frequently with less antibody.[4, 18-22] The percent of responding individuals increases significantly between 12 and 24 months of age.[4, 18, 20, 22] Approximately 90% of children 24 months of age or older produce a significant antibody response to Haemophilus b polysaccharide vaccination, and most of the non-responders have high pre-vaccination titers.[4] The amount of antibody produced by children is also affected by the molecular size of the vaccine: vaccines containing high molecular weight capsular polysaccharide generate more antibody than those with low molecular weight polysaccharide.[24]

The precise protective level of anti-Haemophilus b polysaccharide antibody has not been established. Titers associated with protection of agammaglobulinemic children[18, 20] and experimentally infected animals by passively administered gamma globulin suggest that 0.15 μg/ml is protective. In a controlled field trial, levels ≥1 μg/ml in 3 week post-vaccination serum were correlated with clinical protection[25]; approximately 75% of tested 18-23 month old and 85% of 24-29 month old children achieved that level following Haemophilus b polysaccharide vaccination.[23] These Finnish data can be compared to those obtained with *b*-CAPSA I (see Table 1).

The efficacy of Haemophilus b polysaccharide vaccine was evaluated in a double-blind, controlled field trial conducted in Finland in children 3 months to 5 years of age.[4, 23] Approximately 98,000 children, half of whom received Haemophilus b polysaccharide vaccine, were followed for 4 years. The Haemophilus b polysaccharide vaccine for that study was prepared by the scientific founders of Praxis Biologics. The results indicated that the vaccine was highly protective for children of 18 months to 5 years of age: a single dose reduced the overall attack rate of bacteremic Hib disease by 90%. Of more than 4,000 children who were 18-23 months old when vaccinated, *none* who received Haemophilus b polysaccharide developed bacteremic Hib disease during the four years of follow-up. However, the number of cases of bacteremic Hib disease in the control group was too small to permit a meaningful assessment of Haemophilus b polysaccharide vaccine efficacy in that age group. Children younger than 18 months of age had little immunologic response to the vaccine and were not protected.

Based on the results of their field trial, the Finnish investigators recommended universal vaccination with Haemophilus b polysaccharide for children of ≥18 months of age and suggested the potential need for a booster dose for children who received their primary Haemophilus b polysaccharide vaccination at 18-23 months of age.[4] An analysis of U.S. epidemiological data by clinical investigators at the USPHS Centers for Disease Control supported such use of Haemophilus b polysaccharide vaccine.[3]

Considerable evidence correlates the immunogenicity of bacterial polysaccharide vaccines with their physicochemical properties and the side effects with trace contaminants, especially endotoxin. The properties of *b*-CAPSA I VACCINE are equivalent to those of the Haemophilus b polysaccharide vaccine used in the Finnish field trial. The unique protein-free, chemically defined bacterial growth medium and purification procedures used in the preparation of *b*-CAPSA I VACCINE minimize the content of protein, nucleic acids, and endotoxin and guarantee a large molecular weight.

Table 1 summarizes the antibody responses to *b*-CAPSA I VACCINE.

TABLE 1
ANTIBODY RESPONSES TO VACCINATION WITH *b*-CAPSA I VACCINE

Age (mos.)	No. of Children	Geometric Mean Titer (μg/ml) Pre	Geometric Mean Titer (μg/ml) Post*	Percent of Children with Post-Vaccination Titers ≥1 μg/ml
18-20	34	0.63	1.88	76
24-29	161	0.37	4.30	96
≥30	72	0.24	12.11	100
ALL	267	0.35	5.06	95

**Approximately 3 weeks post-vaccination.*

A limited number of children have been reported to have received DTP and Haemophilus b polysaccharide vaccines at the same time.[22, 24, 26, 27] No impairment of the immune response to individual antigens occurred. The incidence and type of associated reactions[22, 24, 26, 27] approximated those reported for DTP vaccine.[26]

INDICATIONS AND USAGE

b-CAPSA I VACCINE is indicated for immunization of children of 24 months to six years of age against diseases caused by *Haemophilus influenzae* b.

Children of 24 months of age and older have a high rate of seroconversion, and clinical studies indicate that they will be protected against bacteremic Hib diseases following a single vaccination with *b*-CAPSA I VACCINE.

b-CAPSA I VACCINE may be given to children 18-23 months of age known to be at high-risk of systemic Hib disease, e.g., children who attend day care. A controlled field trial suggested that many children in this age group will be protected by a single vaccination, although the rate of seroconversion is not as high as with older children. Parents should be informed that the vaccine is not likely to be completely effective in this age group.

Studies are ongoing to determine the need and timing for revaccination, particularly for children vaccinated at 18-23 months of age.

b-CAPSA I VACCINE *will not protect children younger than 18 months of age and will not protect against* Haemophilus influenzae *other than type b or other microorganisms that cause meningitis or septic disease.*

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CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine, including thimerosal.

WARNINGS

If the vaccine is used in persons deficient in producing antibody, whether due to genetic defect or to immunosuppressive therapy, the expected immune response may not be obtained.

PRECAUTIONS

General

As with the injection of any biological material, epinephrine injection (1:1000) should be available for immediate use should an anaphylactoid reaction occur.

Any febrile illness or active infection is reason for delaying use of *b*-CAPSA I VACCINE.

The vaccine should not be injected intradermally or intravenously, since the safety and efficacy of these routes of administration have not been evaluated. The vaccine should be given *subcutaneously*.

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of hepatitis viruses and other infectious agents from one person to another.

Pregnancy

Pregnancy Category C

Animal reproductive studies have not been conducted with *b*-CAPSA I VACCINE. It is not known whether *b*-CAPSA I VACCINE can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Data are not available to support the use of this product during pregnancy at this time, regardless of benefits.

Nursing Mothers

There is no indication for using this product in nursing mothers.

Pediatric Use

b-CAPSA I VACCINE is not recommended for infants younger than 18 months of age. See comments above about vaccine use in children older than 18 months of age.

ADVERSE REACTIONS

Different preparations of Haemophilus b polysaccharide produced by different procedures and administered at different doses have been evaluated in several field studies. Objectively observed side effects, e.g., erythema and induration at the injection site and fever, have generally been minor and lasted 24 hours or less.[18, 21-23] The incidence of local side effects reported in the Finnish field trial was 51%. In all other reported trials, the incidence of these reactions was 4-9%.[18, 21, 22] Temperatures >38.3°C (101°F) at 24 hours post-vaccination have occurred in up to 13% of vaccinated children. In the Finnish field trial, one child had a possible anaphylactoid reaction; following an injection of epinephrine, the child recovered rapidly and without complications.

The side effects associated with the use of *b*-CAPSA I VACCINE in children are summarized in Table 2. At 24 hours post-vaccination, local reactions were observed in 1.5% of vaccinated children, and temperature >38.3°C (101°F) in 0.75%.

TABLE 2
SIDE EFFECTS AT 24 HOURS ASSOCIATED WITH VACCINATION OF CHILDREN (18-60 MOS.) WITH *b*-CAPSA I VACCINE

No. of Children	Temperature >38.3°C (101°F)	Objective Local Reaction Swelling	Objective Local Reaction Erythema
267*	2	4	4

**161 of these children were 24-29 months at vaccination.*

DO NOT INJECT INTRAVENOUSLY.

The immunizing dose is a single injection of 0.5 ml of reconstituted *b*-CAPSA I VACCINE given subcutaneously.

b-CAPSA I VACCINE is manufactured by Praxis Biologics, Inc., Rochester, New York 14623 and distributed by Mead Johnson Nutritional Division, Evansville, Indiana 47721.

For information contact: MEAD JOHNSON NUTRITIONAL DIVISION at (812) 426-7480.

Reference list will be supplied by Mead Johnson upon request.

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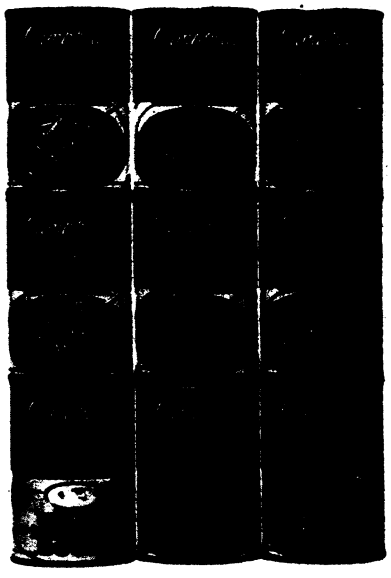

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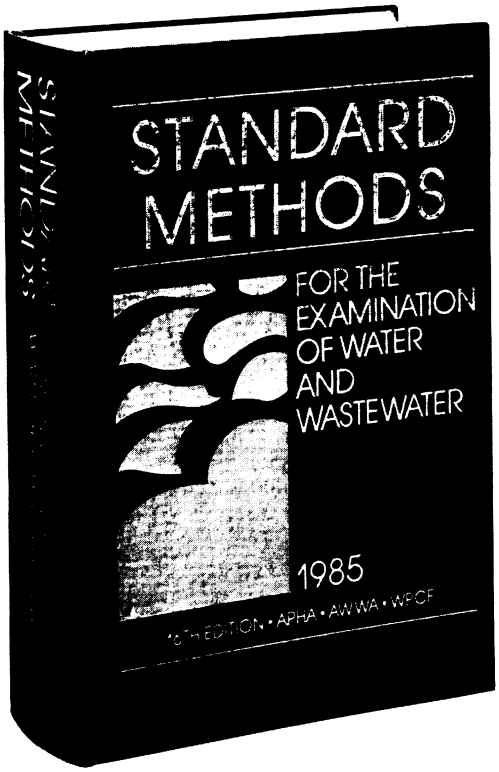

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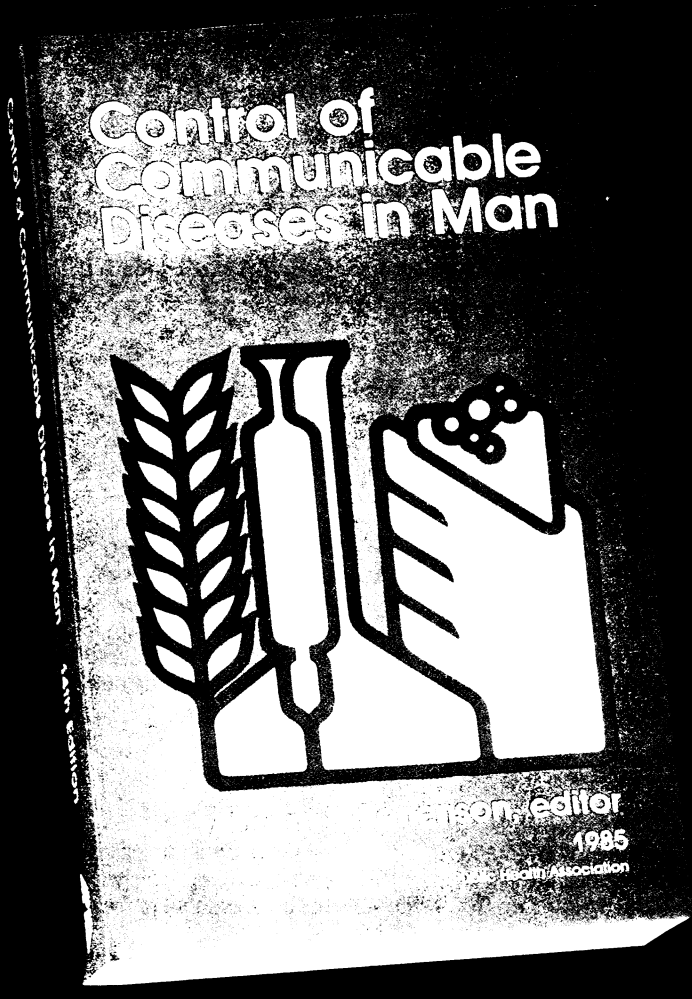

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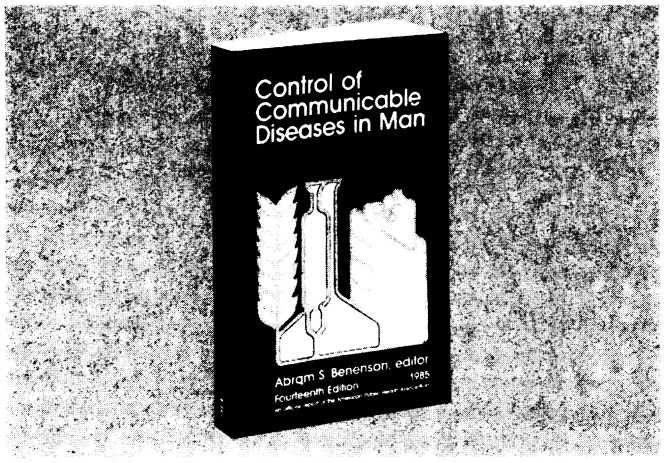

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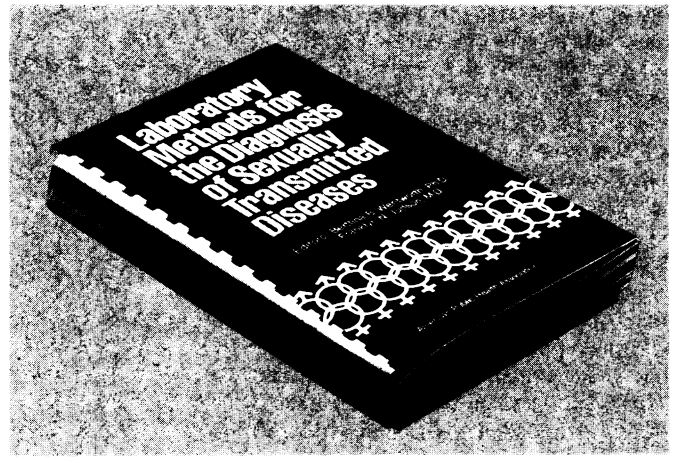

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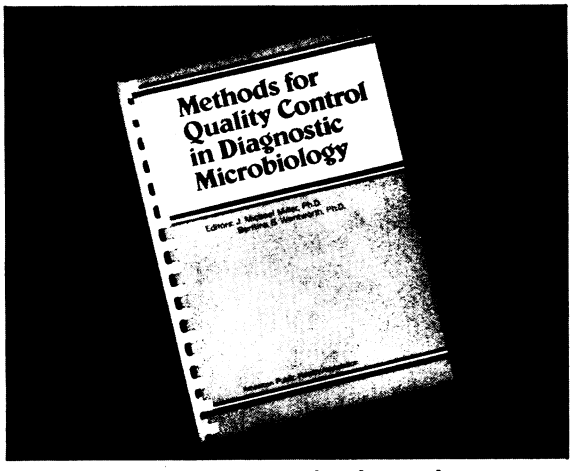

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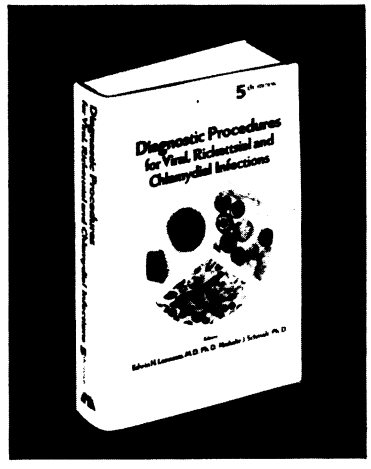

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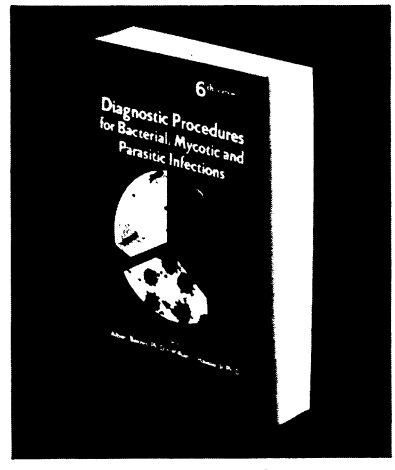

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December	**Oct. 1**	**Nov. 20**

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A 50% discount is offered to APHA Agency Members. For information on agency membership, contact: Director, Membership Services, APHA, 1015 Fifteenth St., NW, Washington, DC 20005.

Ads received after the closing date will be placed in the next available issue unless otherwise indicated.

All ad copy and correspondence should be sent to:

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☐ Positions Available ☐ Positions Wanted $ _____ Amount Enclosed

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TRADE PAPER MANAGEMENT FOR PEOPLE MANAGEMENT

Effective administrators channel their time and effort into managing people—providing the guidance, counsel and planning that are necessary to keep an organization running smoothly. Unfortunately, the myriad of paperwork required to satisfy government regulations and third party payers is forcing more and more of the manager's attention from people management to paper management. CMHC can help reverse this trend with the Public Health Information Management System.

The CMHC Information Management System is designed specifically for public health organizations. This computer-aided system greatly simplifies even the most complex record keeping and reporting. It maintains up-to-the-minute patient records and prepares the necessary reporting forms automatically.

The Public Health Management Information System from CMHC features Texas Instruments computers.

The System also increases cash flow by speeding the preparation—while increasing the accuracy of billing. And, the system can be formatted to meet most billing requirements.

The CMHC Public Health Management Information System automatically updates receivables, payables, payroll and other financial matters. At the same time, it supplies management with timely reports on virtually every facet of the organization's operation.

For more details, without obligation, call us direct at **1-614-764-0143.**

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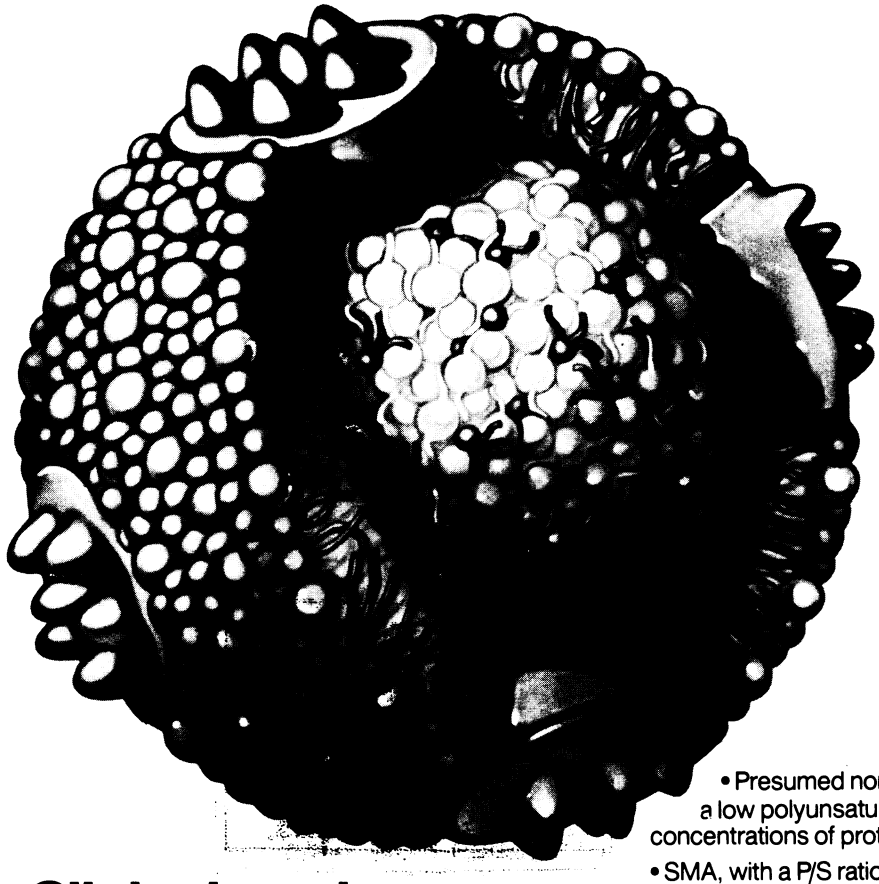
CMHC HELPS YOU MANAGE YOUR PEOPLE MORE EFFICIENTLY AND EFFECTIVELY

HDL: the protective lipoprotein

HDL (high-density lipoprotein) has been called the "good" lipoprotein because unlike LDL (low-density lipoprotein), which promotes fatty deposits in the blood vessels, HDL helps eliminate cholesterol from the body. Because of this, researchers have noted that persons with higher levels of HDL have a lower rate of heart disease.



Medical artist's visualization of HDL as it might appear while circulating in blood or plasma.

Clinical study: SMA® produces high HDL levels virtually identical to breast milk.

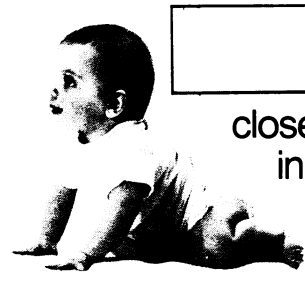
- Presumed normolipemic infants fed human milk with a low polyunsaturated to saturated (P/S) fat ratio had high concentrations of protective HDL cholesterol.[1]
- SMA, with a P/S ratio virtually identical to breast milk, maintained the high level of HDL cholesterol closest to that of human milk.
- Infant formula with a high P/S ratio significantly lowered the level of HDL cholesterol compared with human milk and SMA.

Reference:
1. Carlson SE, DeVoe PW, Barness LA: Effect of infant diets with different polyunsaturated to saturated fat ratios on circulating high-density lipoproteins. J Pediatr Gastroenterol Nutr 1:303-309, 1982.

Important Notice. Breast milk is best for babies. Infant formula is intended to replace or supplement breast milk when breast-feeding is not possible or is insufficient, or when mothers elect not to breast-feed.

Good maternal nutrition is important for the preparation and maintenance of breast-feeding. Extensive or prolonged use of partial bottle-feeding, before breast-feeding has been well established, could make breast-feeding difficult to maintain. A decision not to breast-feed could be difficult to reverse.

Professional advice should be followed on the need for and proper method of use of infant formula and on all matters of infant feeding. Infant formula should always be prepared and used as directed. Unnecessary or improper use of infant formula could present a health hazard. Social and financial implications should be considered when selecting the method of infant feeding.



SMA® INFANT FORMULA

closest to breast milk in all nutritional components

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